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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,245	11/15/2001	Jens Holm	4305/1H942-US2	9286

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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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02/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/001,245

Applicant(s)

HOLM ET AL.

Examiner

Nora M. Rooney

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22,35,37-39,64 and 66-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22,35,37-39,64 and 66-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-15, 18, 21-22, 35, 64 and 66-82 drawn to a recombinant mutant Fagales group 1 allergen and a composition thereof, classified in Class 53, subclass 350, Class 424, subclass 185.1, and Class 514, subclass 2.

II. Claim 1-15, 19, 35, 64 and 66-82 drawn to a recombinant mutant Vespidae antigen 5 allergen and a composition thereof, classified in Class 53, subclass 350, Class 424, subclass 185.1, and Class 514, subclass 2.

III. Claim 1-15, 20, 35, 64 and 66-82 drawn to a recombinant mutant house dust mite group 1 allergen and a composition thereof, classified in Class 53, subclass 350, Class 424, subclass 185.1, and Class 514, subclass 2.

IV. Claim 1-15, 17, 35, 64 and 66-82 drawn to a recombinant mutant house dust mite group 2 allergen and a composition thereof, classified in Class 53, subclass 350, Class 424, subclass 185.1, and Class 514, subclass 2.

V. Claim 1-16, 35, 64 and 66-82 drawn to a recombinant mutant grass group 5 allergen and a composition thereof, classified in Class 53, subclass 350, Class 424, subclass 185.1, and Class 514, subclass 2.

VI. Claims 1, 37-39, 83-85 drawn to a composition comprising two or more recombinant mutant allergens; classified in Class 53, subclass 350, Class 424, subclass 185.1, and Class 514, subclass 2.

2. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. This application contains claims directed to the following patentably distinct species:

If Applicant elects Group I, Applicant is required to elect:

a single specific allergen as recited in claims 18 and 21 (Bet v 1, Aln g 1, Cor a 1 or Car b 1) ; and

if Bet v 1 is elected in claims 18 and 21, then a single specific mutant Bet v 1 molecule comprising all of its specific, defined mutations as set forth in claim 22.

If Applicant elects Group II, Applicant is required to elect:

a single specific allergen as recited in claim 19 (Ves v 5 or Pol a 5)

If Applicant elects Group III, Applicant is required to elect:

a single specific allergen as recited in claim 20 (Der p 1 , Def f 1 or Lep d 1)

If Applicant elects Group IV, Applicant is required to elect:

a single specific allergen as recited in claim 17 (Der p 2, Der f 2 and Lep d 2)

If Applicant elects Group V, Applicant is required to elect:

a single specific allergen as recited in claim 16 (Lol p 5, Phl p 5, Poa p 5 or Sec c 5)

If Applicant elects Group VI, Applicant is require to elect:

two or more specific allergens as recited claims 18 and 21 (Bet v 1, Aln g 1, Cor a 1 or Car b 1), claim 19 (Ves v 5 or Pol a 5), claim 20 (Der p 1 , Def f 1 or Lep d 1), claim 17 (Der p 2, Der f 2 and Lep d 2); and claim 16 (Lol p 5, Phl p 5, Poa p 5 or Sec c 5); and

if Bet v 1 is elected in claims 18 and 21, then a single specific mutant Bet v 1 molecule comprising all of its specific, defined mutations as set forth in claim 22.

Please note, the elected allergen molecules must be specifically defined such that the Examiner may search for that exact, defined molecule having specified mutations at disclosed locations in the molecule.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries);

and/or the prior art applicable to one species would not likely be applicable to another species;
and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 31, 2008

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

MaHer M. Haddad
MAHER M. HADDAD
PRIMARY EXAMINER